邀请函 Invitation

美国药典委员会中华区总部诚挚地邀请您参加以下药典培训课程
USP-China sincerely invites you to attend the following USP Pharmacopeial Education course.

美国药典微粒标准
Introduction to Compendial Particulate Matter Standards

课程日期 Date:

2023 年 8 月 22 日　中国上海
Aug. 22, 2023　Shanghai China

课程简介 Course Description:

无菌注射产品的微粒测定已有 30 多年的历史，然而，最近对敏感蛋白药物标准方法的改进为药典标准带来了变化和其他背景信息。课程全面介绍可见微粒、亚可见微粒、灰色区域微粒的美国药典标准和相关法规指南。内容涵盖 USP 可见微粒测定和两个相关通则<790>注射剂中可见微粒检查、<1790>注射剂的目视检查，亚可见微粒相关通则<788>注射剂中微粒检查、<1788>亚可见微粒测定方法、<787>治疗性蛋白注射液中亚可见微粒检查、<1787>治疗性蛋白注射液中亚可见微粒物的测定、<771>眼用产品-质量检测、<789>眼用溶液剂中微粒检查，以及 USP 通则的灰区注意事项、风险和实践考量等。

通过学习，您将能够：

- 了解微粒物与注射剂概述
- 学习亚可见和可见的微粒测定方法
- 应用实验室配置和样品制备方法
- 了解 USP 通则<1>注射剂相关主题与通则<788>和<790>之间的关联
- 定义目视检查的灰色区域

Particle determination for sterile injectable products has been required for more than 30 years; however, recent improvements in standard methods for sensitive protein products have brought changes and additional background information to the Compendial guidance. This course will discuss the current <788> Particulate Matter in Infections and <1788> Methods for the Determination of Subvisible Particulate Matter, requirements for sub-visible particle determination. And a discussion on the new General Chapter <787>Subvisible Particulate Matter in Therapeutic Protein Injections for particle determination in protein formulations and the informational Chapter <1787> Measurement of Subvisible Particulate Matter in Therapeutic Protein Injections which provides background and rationale for sub-10µm characterization. In addition, General Chapter <771> Ophthalmic Products—Quality Tests and <789> Particulate Matter in Ophthalmic Solutions will be introduced. A portion of the course will focus on visible particle determination and the two new Compendial chapters on the topic <790> Visible Particulates in Injections and <1790> Visual Inspection of Injections, together with the Gray Zone.
Upon completion of this course, you will be able to:

- Outline Perspectives Regarding Particulate Matter and Injectable Products
- Outline Particulate Matter Determination Methods, both subvisible and visible
- Apply lab configuration and sample preparation methodologies
- Relate USP Chapter <1> Injections' topics relevant to <788> and <790>
- Define the gray zone for visual inspection

报名请登录USP会议与培训中文平台，点击这里（课程报名）在线报名（报名截止日：2023年8月16日）

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参加对象 Who Should Attend:

与注射剂产品检查相关的生产和操作人员，从事对被检产品进行抽样检验或审核检验数据的质量和监管人员，从事符合 cGMP 要求和与注射剂相关的监管申报人员，制药及其相关行业的实验室科学人员、实验室经理、QA/QC 人员，以及对微粒物感兴趣的科学人员。

Manufacturing/Operations Personnel who are responsible for the inspection of injectable products, Quality and Regulatory Personnel who are responsible for the sampling inspection of inspected products or the review of inspection data, and those responsible for compliance with cGMP and regulatory filings associated with injectable products. Laboratory scientists, Lab managers, QA/QC staff in the pharmaceutical and allied industries, Scientists with interest in Particulate Matter.

授课语言 Language:

英语（现场中文口译、双语书面讲义）

English (Chinese Interpretation and bilingual printed teaching materials)

讲师介绍 Instructor:

Desmond G. Hunt 博士，美国药典委员会科学部门通则标准资深首席科学家

Desmond G. Hunt, Ph.D., Senior Principal Scientific Liaison, Science - General Chapters, USP US

Hunt博士负责协助 USP“包装、储存与流通专家委员会”、“制剂专家委员会”建立公共标准。他与工业界、学术界、监管机构和其他科学组织紧密联系，致力于药典通则的制定和修订工作。他有超过20年的丰富科研经验。在加入USP之前，Hunt博士是美国马里兰毕士大国家卫生研究院研究员。他领导了多项开发和建立用于药物包装系统材料公共标准的研究。他也是产品质量研究所包装和可提取物和浸出物工作组成员。Hunt博士在美国德州大学奥斯汀分校获得理学硕士和博士学位。

Dr. Hunt is responsible for assisting USP Expert Committees, Packaging, Storage and Distribution and Dosage Forms, in the development and revision of USP Standards. Dr. Hunt has over 20 years of research experience and prior to joining USP, he was a Research Fellow at the National Institutes of Health, Bethesda, MD, USA. Dr. Hunt has conducted a number of studies relating to the development and establishment of public standards for materials used for pharmaceutical packaging. He is a member the Product Quality Research Institute Container-Closure and Extractable and Leachable Working Groups. He obtained his Master of Science and Doctoral Degree from the University of Texas at Austin, USA.

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课程纲要 Course Outline:

- **微粒概览 Overview of Particulate Matter**
  - 定义、来源、分类、USP 相关标准和指南
    Historical Definition, Sources, Classification, Compendial Standards and Guidance
- **可见微粒 Visible Particles**
  - USP 通则<1>“注射剂和植入药物（注射用）– 产品质量测试”及要点
    USP <1> *Injections and Implanted Drug Products (Parenteral) – Product Quality Tests*, and Key Points
  - USP 通则<790>“注射剂中可见微粒检查”及要点
    USP <790> *Visible Particulates in Injections*, and Key Points
  - USP 通则<1790>注射剂的目视检查 USP <1790> *Visual Inspection of Injections*
    - 关键主题和要点 Key Topics and Key Points
    - 典型检查流程 Typical Inspection Process Flow
    - 检查过程的确认和验证 Qualification and Validation
    - 培训和资格认证 Training and Qualification
  - 其他相关指南 Other Relevant Guidance
    - FDA/EMA/EP/PDA 可见微粒指南 FDA/EMA/EP/PDA
- **亚可见微粒 Subvisible Particles**
  - 亚可见微粒通则和药典方法的演变 Subvisible Chapters and Evolution of Compendial Methods
  - 药典方法要求 Compendial Method Requirements
  - 主要方法：光阻法、膜显微镜法、流动成像法
    Primary Methods: Light Obscuration, Membrane Microscopy, Flow Imaging
  - 其他方法：Other Methods
    - USP 通则<1787>治疗性蛋白注射液中亚可见微粒的测定
      USP <1787> *Measurement of Subvisible Particulate Matter in Therapeutic Protein Injections*
    - 批次取样 Lot Sampling
- **眼用产品 – USP 通则<771>和<789> Ophthalmic Products - USP General Chapters <771> and <789>**
  - USP 相关通则修订历史、<771>重大修订 Revision History and <771> Major Revision
  - 眼用制剂的可见微粒和异物
    Visible Particulate and Foreign Matter in Ophthalmic - Visual Inspection & Alternatives
  - 眼用制剂中的亚可见微粒和异物 Subvisible Particulate and Foreign Matter in Ophthalmic
    - 亚可见微粒检测方法：通则<788>、<789> Subvisible Methods: <788>, <789>
- **灰色区域 The Gray Zone**
  - 定义灰色区域 Defining the Grey Zone
    - Knapp 方法 Knapp Methodology
    - USP 通则的灰区注意事项 Gray Zone Considerations in USP Chapters
    - 微粒风险注意事项 Particle Risk Considerations
  - 实践考量 Practical Considerations
  - 难以检查产品的补充检测 Supplemental Testing for Difficult to Inspect Products

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课程日程 Agenda:

时间 Time	主题 Topic	
9:00 am - 12:00 pm	微粒概览	Overview of Particulate Matter
	可见微粒	Visible Particles
	亚可见微粒	Subvisible Particles
12:00 pm - 13:00 pm	*午餐*	*Lunch*
13:00 pm -17:00 pm	亚可见微粒（续）	Subvisible Particles (cont.)
	眼用产品 – USP 通则<771>和<789>	Ophthalmic Products - USP General Chapters <771> and <789>
	灰色区域	The Gray Zone

This agenda is subject to change. 此表仅供参考，具体日程以现场课程为准

培训地点 Location:

上海大酒店 Grand Central Hotel Shanghai

地址：上海市九江路 505 号（地铁 2 号线、10 号线，南京东路站 4 号口，步行距离约 200 米）

电话：021 53538888

备注：培训课不统一安排住宿，请自行联系酒店订房。（若需要，可联系我们了解周边酒店信息供参考）

培训费用 Fee：2,000 元人民币/人 RMB 2,000/person

注：1、费用包含培训费、资料费、日程表中提及的餐饮费；其它费用自理。
Including training, teaching materials, and food indicated in the agenda only.

2、若同一公司/单位选派 3 名以上人员参加此次培训，自第三人起可享 20%折扣。
The 3rd and more people from the SAME COMPANY can get 20% discount.

3、政府药检系统单位或科研院校，享 20%折扣。
20% discount is offered to applicants from Government Labs and Universities.

报名方式 Register Procedures:

1. 在线报名、缴费（截止日：2023 年 8 月 16 日） Make online registration and payment by Aug. 16, 2023.

   请点击这里（课程报名）进行在线报名 Click **here** for online registration.

   USP-China 人民币收款账户： USP-China account (RMB)

   收款人： 美药典标准研发技术服务（上海）有限公司
   账号： 6841 12464 120
   银行： 美国银行有限公司上海分行

2. 发票领取：培训课当天签到时领取，或课后快递提供
   Invoice is available at the Registration Desk of training room or after the course.

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